UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., Quincy Bioscience Manufacturing, LLC (collectively "Quincy"), and Mark Underwood[1] (collectively with Quincy, "Defendants") hereby submit this reply memorandum of law in further support of their Motion for Summary Judgment (Dkt. 227) ("Motion" or "Mot.") and Statement of Material Facts (Dkt. 221) ("SOF") filed April 14, 2022, and in response to Plaintiffs Opposition (Dkt. 255) ("Opposition" or "Opp.") and Counterstatement of Material Facts (Dkt. 257) ("CSOF") filed June 16, 2022. Defendants are also filing herewith a Reply Statement of Materials Facts ("RSOF").

PRELIMINARY STATEMENT

Plaintiffs—the Federal Trade Commission and the New York Attorney General—have been investigating Defendants (and then litigating against them) for seven years at this point. But after all that time, after the extensive investigation, after the endless motions, after all of the fact and expert discovery, including scores of depositions, Plaintiffs have no competent evidence whatsoever to create a material dispute of fact on the key elements of their claims, and summary judgment must be granted. Most importantly, not one of Plaintiffs' experts opined as to whether Quincy satisfied the FTC's own standard for advertising claims about dietary supplements. Because Plaintiffs' only challenges to Defendants' Motion (1) rely on expert opinion that is not relevant to Quincy's substantiation burden, or (2) are based on factually unsupported, conclusory arguments, Plaintiffs have not shown any legally relevant disputes of material fact, and Defendants' Motion should be granted.

[1] Mr. Underwood participates in this reply brief only as to the claims asserted by the FTC because the claims by the NYAG against Mr. Underwood have been dismissed with prejudice. (Dkt. 272.)

Defendants' Motion established that the Challenged Claims are substantiated "structure/function" claims and that Quincy's scientific substantiation far exceeds what is required by law. (Mot. at 18—31.) In their Opposition, Plaintiffs finally—and for the first time in this Action—essentially concede that the FTC Guidance[2] governs the substantiation standard for the Challenged Claims. (CSOF ¶¶ 1, 59—63, 147; Opp. at 10, 12—15 (stating "competent and reliable scientific evidence" standard is the "flexible" standard "set forth in the FTC Guidance").) That admission dooms Plaintiffs' case because *none* of Plaintiffs' experts were even aware of the FTC Guidance when they rendered their opinions in this matter and *none* of them considered the substantiation standard set forth therein for dietary supplements. Plaintiffs cannot satisfy their burden of establishing that there is a dispute of material fact as to whether the Challenged Claims are adequately substantiated or whether the Challenged Claims are "likely to mislead consumers acting reasonably under the circumstances." Defendants are therefore entitled to summary judgment on all counts.

Undeterred, Plaintiffs attempt to shoehorn their subjective, heightened drug-level RCT requirement into the FTC Guidance. But the FTC Guidance for dietary supplement companies does not require RCTs, let alone the specific drug-level RCT design that Plaintiffs and their experts seek to impose retroactively on Quincy. Plaintiffs' attempt to reinvent the substantiation standard through their experts has been rejected multiple times and should be rejected again as inconsistent with the relevant law and FTC Guidance, and violative of Defendants' Due Process rights.

Plaintiffs' attempts at attacking the specific studies that comprise Defendants' substantiation of the Challenged Claims fall far short. Plaintiffs' Opposition fails to identify any *genuine* disputes of material fact regarding the Madison Memory Study or any of the other

[2] Defined terms herein have the same meaning as those defined in Defendants' opening brief unless otherwise noted.

substantiation offered by Defendants. Plaintiffs may disagree with Defendants' proposed material facts, but mere disagreement, legal argument, objections, and unsupported expert assumptions do not create triable issues of fact or preclude summary judgment. Because Plaintiffs have failed to *genuinely* dispute nearly all of Defendants' proffered facts regarding the substantiation for the Challenged Claims, summary judgment is warranted in Defendants' favor.

Plaintiffs also failed to offer any evidence whatsoever as to how consumers interpreted Quincy's marketing claims, arguing instead that they have no such burden. In fact, Plaintiffs' Opposition actually *confirms* the need for such evidence given Plaintiffs' assertions that the terms "clinical" and "RCT" are vague and ambiguous. Therefore, Plaintiffs should have offered extrinsic evidence of how consumers perceived Quincy's "clinically shown" marketing claims. Nor is this Court required to accept Plaintiffs' self-serving characterizations of the *Collins* Qualifier, absent any corroborating consumer perception evidence. Plaintiffs' tactical litigation decision not to offer any extrinsic evidence of consumer perception should be fatal to their claims.

Plaintiffs' interpretation of Section 13(b) of the FTC Act is yet another example of the FTC's litigation shortcuts. In *AMG Capital Management, LLC v. FTC*, 141 S. Ct. 1341 (2021), the Supreme Court questioned the FTC's ability to obtain a permanent injunction when it had not previously sought or obtained a preliminary injunction at the outset of litigation. Plaintiffs ignore both the Supreme Court's discussion from *AMG* and the plain language of the FTC Act, and instead continue to cling to outdated, non-binding precedent that holds otherwise. This Court should carefully review the text of Section 13(b), give appropriate deference to the Supreme Court's recent pronouncement, and enter summary judgment for Defendants because the FTC admittedly failed to seek a preliminary injunction at the outset of this case.

The NYAG's response to Defendants' preemption and safe harbor arguments—that FDA law does not apply and therefore cannot preempt its claims—is similarly meritless. Throughout this Action, Plaintiffs have affirmatively paid deference to FDA law and DSHEA through their continued reliance on a (subsequently closed) FDA warning letter. Thus, the NYAG's argument that DSHEA (and the FTC Guidance) does not preempt their claims or trigger Defendants' safe harbor defense is irreconcilable with their own conduct in this litigation and simply wrong.

Finally, the NYAG's feigned opposition to Defendants' position on restitution demonstrates that Plaintiffs are determined to disagree with everything Defendants say in an attempt to create an issue of fact that would defeat summary judgment when there is nothing for them to dispute. But the parties *agree* that the NYAG is not entitled to restitution on behalf of New York residents who purchased Prevagen® prior to the *Collins* Settlement. Summary judgment should be entered accordingly in Defendants' favor with respect to each of Plaintiffs' claims, which should all be dismissed with prejudice.

ARGUMENT

I. PLAINTIFFS FAILED TO CONTEST A MAJORITY OF DEFENDANTS' PROFFERED MATERIAL FACTS, WHICH SHOULD BE DEEMED ADMITTED

Plaintiffs' response to Defendants' Statement of Material Facts is, at best, woefully deficient and, at worst, a flagrant disregard of Local Rule 56.1. That Rule is crystal clear: in order to contest a fact set forth in the moving party's Rule 56.1 statement, the non-moving party must "specifically controvert" that fact, and the statement controverting that fact must be followed by a citation to record evidence. Local. Civ. R. 56.1(c), (d). Any fact that is not "specifically controverted" will be "deemed to be admitted." Local Civ. R. 56.1(c). Conclusory denials that are not supported by citations to record evidence—the vast majority of Plaintiffs' denials here—are insufficient. *See Thompson v. Glob. Contact Servs., LLC*, No. 20-CV-651, 2021 WL 3486944,

at *2 (E.D.N.Y. July 21, 2021), *report and recommendation adopted*, No. 20-CV-651, 2021 WL 3476675 (E.D.N.Y. Aug. 6, 2021); *see also I.M. v. United States*, 362 F. Supp. 3d 161, 173 n.8 (S.D.N.Y. 2019). All such improperly "contested" facts should be deemed admitted.

First, Plaintiffs have lodged objections to various facts as "immaterial," "vague," or "incomplete" without citations to any record evidence that refute their truth. These objections do not "specifically controvert" the asserted facts. *See Schmelczer v. Penn Credit Corp*., No. 20-CV-2380, 2022 WL 862254, at *1 n.1 (S.D.N.Y. Mar. 23, 2022) ("[W]hen a Party objects to the inclusion of a statement solely on the basis that the statement asserts a fact that is 'immaterial,' the Court will not consider this technicality as creating a dispute."); *Southside Hosp. v. New York State Nurses Ass'n*, No. CV-15-2282, 2017 WL 9485721, at *3 (E.D.N.Y. Jan. 26, 2017) (objection alone does not controvert fact), *report and recommendation adopted*, No. 15-CV-2282, 2017 WL 837673 (E.D.N.Y. Mar. 3, 2017). Plaintiffs' violations of Local Rule 56.1 permeate their response. For example, in response to Defendants' proffered fact that the phrase "dietary supplement" has been on every bottle of Prevagen sold, Plaintiffs argue that the asserted fact is "irrelevant and immaterial" and that "Defendants have not produced every package or label of Prevagen sold since 2007." (CSOF ¶ 13; *see also* ¶¶ 14, 52.) In the same conclusory manner, Plaintiffs purport to contest facts surrounding Defendants' settlement of the *Collins* litigation (*id.* ¶¶ 39—44), Quincy's consultation with outside counsel in connection with its advertising claims (*id.* ¶¶ 74—76), Quincy's open-label trials (*id.* ¶¶ 89—90), Defendants' experts' qualifications (*id.* ¶ 121), and the testimony of Plaintiffs' own experts (*id.* ¶¶ 124—128)—all simply by resorting to objections. Because they cite no record evidence in their responses and rely only on bare conclusory objections, Defendants' proposed facts should be deemed admitted.

Second, Plaintiffs respond to a number of Defendants' facts with legal argument, which is not only out of place but "unhelpful" in a Rule 56.1 statement and should be disregarded. *See Valade v. City of New York*, 949 F. Supp. 2d 519, 521 n.1 (S.D.N.Y. 2013); *Trustees of Loc. 8A-28A Welfare Fund v. Am. Grp. Administrators*, No. 14-CV-1088, 2017 WL 3700899, at *4 (E.D.N.Y. Aug. 25, 2017). For example, in response to Defendants' assertion that it agreed to add the Qualifier to its labeling as part of the *Collins* settlement, Plaintiffs cite inapposite *case law* to argue that a disclaimer does not necessarily cure an allegedly deceptive ad, yet offer no *evidence* of the effect of the Qualifier on consumers' net impression of Quincy's advertising. (CSOF ¶ 45.) In fact, they have not offered any evidence from any consumer in this action. Instead, Plaintiffs simply argue their position. Such uncontroverted facts therefore should be deemed admitted.

And *third*, Plaintiffs purport to contest facts by citing to record evidence that in no way disputes the fact asserted, and in some cases is *consistent* with the fact set forth by Defendants. For example, Plaintiffs "contest" Defendants' statements that the advertisements featured in the Complaint are no longer being disseminated in that form by citing irrelevant material (other advertisements) and including unsupported argument in an attempt to support their assertion that the "disclaimer does not cure the deceptive net impression of Defendants' ads." (*Id.* ¶¶ 26, 29, 50.) Plaintiffs couple those irrelevant assertions with improper argument regarding their *legal* contentions in this case: that Quincy is making claims that are similar to the ones that were made in those advertisements. (*Id.*) But nowhere in Plaintiffs' response is any evidence showing that the advertisements attached to the Complaint are being disseminated in the same form today or that Defendants intend to resume dissemination of them in the future.

Many of Plaintiffs' other responses likewise do not address the substance of Defendants' proposed facts. For example:

- Defendants stated that Prevagen's target market is older, healthy adults who are cognitively normal or who have mild cognitive impairment. In response, Plaintiffs cite an FDA warning letter that contains *unproven allegations* (CSOF ¶ 16) and ignore that the FDA closed that warning letter. (Graham Reply Decl. Ex. QQ.)

- Defendants stated that they entered into a research agreement with a laboratory at the University of Wisconsin-Milwaukee and that the laboratory has conducted studies on apoaequorin in animal models. In response, Plaintiffs do not contest the existence of the research agreement or studies, but cite to their experts' unsupported opinions that "[s]tudies conducted in animal models are insufficient to substantiate the advertising claims at issue in this case." (CSOF ¶ 83; *see also* ¶¶ 84—87.)

- Defendants stated that Plaintiffs have not issued any guidance or regulation prohibiting subgroup analyses. In response, Plaintiffs cite language in the FTC Guidance that does not even mention subgroups. (*Id.* ¶ 77; *see also* ¶¶ 78—79 (same for Defendants' statements that Plaintiffs have not issued guidance regarding the required level of statistical significance for efficacy claims).)

- Defendants stated that an open-label trial showed a benefit on questions related to cognitive function. In response, Plaintiffs assert that "[d]emonstrating efficacy requires comparison of a treatment to a control." (*Id.* ¶ 91.)

- Defendants stated that the journal, *Advances in Mind Body Medicine*, published a peer-reviewed paper that reported on a subset of results from the Madison Memory Study. In response, Plaintiffs do not contest the peer-reviewed publication but argue, without citing evidence, that the journal has a "low 'impact factor.'" (*Id.* ¶ 115.)

- Defendants stated that Plaintiffs' experts were not familiar with the "competent and reliable scientific evidence" standard set forth in the FTC Guidance. In response, Plaintiffs cite to their experts' purported expertise in the fields of cognition and biostatistics. (*Id.* ¶¶ 129—131.)

- And, finally, and perhaps most egregiously, in response to Defendants' statement that their experts evaluated Quincy's scientific substantiation in accordance with the "flexible, totality of the evidence approach set forth in the Guidance" and that their experts concluded that the Challenged Claims were substantiated, Plaintiffs baldly state that Defendants' experts did not do so and cite only to nine pages of the FTC Guidance. (*Id.* ¶ 122.)

In short, Plaintiffs are "speaking past" Defendants' material facts. *Baity v. Kralik*, 51 F. Supp. 3d 414, 418 (S.D.N.Y. 2014). Because Plaintiffs often cite no evidence at all (and when they do cite evidence, that evidence does not actually contest the facts asserted by Defendants),

those facts should be deemed admitted. *See Red Pocket, Inc. v. Interactive Commc'ns Int'l, Inc*., No. 17-CV-5670, 2020 WL 838279, at *1 n.1 (S.D.N.Y. Feb. 20, 2020) ("Where the Parties identify disputed facts but with semantic objections only or by asserting irrelevant facts, these purported disputes, which do not actually challenge the factual substance described in the relevant paragraphs, the Court will not consider them as creating disputes of fact.").

As set forth herein, this Court should reject Plaintiffs' attempt to create material issues of disputed fact where none exist, and grant summary judgment in Defendants' favor.

II. THE CHALLENGED CLAIMS ARE SUBSTANTIATED BY COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE

A. Plaintiffs' Experts Did Not Review Defendants' Substantiation In Accordance With The Relevant Standard For Dietary Supplements

Despite the FTC's own Guidance, which makes clear that the "competent and reliable scientific evidence" substantiation standard *for dietary supplements* is "flexible," permitting consideration of many different types of research, Plaintiffs have taken the absurd position that the phrase "dietary supplement" has no legal meaning or application in this case. (CSOF ¶¶ 11, 80, 109.) Rather, Plaintiffs ask this Court to adopt a new, heightened drug-level RCT requirement that is plainly inconsistent with the flexible standard set forth in the FTC Guidance. (SOF ¶¶ 67—73; Graham Decl. Ex. F, FTC Guidance at 9-18). This demand by the FTC for a heightened requirement has been rejected by other Courts. (Mot. at 20—23) (discussing *FTC v. Garden of Life, Inc.*, 516 Fed. App'x 852, 854-58 (11th Cir. 2013); *United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595, at *3-4 (D.N.J. Sept. 24, 2015); *Basic Rsch., LLC v. FTC*, No. 2:09-cv-0779, 2014 WL 12596497, at *9-11 (D. Utah Nov. 25, 2014)).)

In recognition of this deficiency, Plaintiffs now attempt an about-face, admitting (finally) that the "competent and reliable scientific evidence" standard set forth in the FTC Guidance is the controlling standard. (CSOF ¶¶ 1, 59—63, 147; Opp. at 10, 12—15.) This admission alone is

sufficient to award summary judgment to Defendants on all counts because there is no dispute that Plaintiffs' experts failed to consider the FTC Guidance and the "competent and reliable scientific evidence" standard in forming their opinions. Their opinions, therefore, do not reflect a review of the evidence in accordance with the relevant standard. (CSOF ¶¶ 59—73, 122—130.)[3] *See Virgin Atlantic Airways Ltd. v. British Airways PLC*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999), *aff'd,* 257 F.3d 256 (2d Cir. 2001) ("expert testimony without . . . a factual foundation cannot defeat a motion for summary judgment."); *Basic Rsch.*, 2014 WL 12596497, at *10 (awarding summary judgment where the FTC's expert applied the incorrect standard with respect to dietary supplement substantiation).

B. The Challenged Claims Are Substantiated Structure/Function Claims Under The FTC Guidance, Which Does Not Require The Drug Level RCT Advanced By Plaintiffs

1. Plaintiffs' Drug-Level RCT Requirement Is Not In the FTC Guidance

Plaintiffs now argue that a drug-level RCT requirement is consistent with the FTC Guidance to substantiate structure/function claims. (Opp. at 6—15.) They are wrong. Confronted with the sound reasoning in *Bayer*, *Basic Research*, and *Garden of Life*—all cases that rejected prior attempts by the FTC to hold dietary supplement manufacturers to a higher substantiation standard for structure/function claims—Plaintiffs limit their attempt at distinguishing these cases to a single-statement: that they are "inapposite" because they involved issues regarding whether those "defendants violated a specific provision of a prior court order *that did not expressly mention RCTs*.[4]" (Opp. at 11) (emphasis added.) Plaintiffs' dismissal of the three most salient decisions

[3] These facts are either uncontested (CSOF ¶¶ 59—64, 70), "contested" but unsupported by evidence that actually refutes Defendants' proffered fact (CSOF ¶¶ 65—69, 71—73, 122—123, 130), or "contested" and objected to as immaterial (CSOF ¶¶ 124-129). They should all be deemed admitted.

[4] *Basic Research* was decided on summary judgment.

on the proper application of the "competent and reliable scientific evidence" standard as to *structure/function claims* for *dietary supplement products* should not go unnoticed for at least four separate reasons.

First, the definition of "competent and reliable scientific evidence" at issue in *Bayer*, *Basic Research*, and *Garden of Life* is the exact same definition set forth in the FTC Guidance. *See Bayer*, 2015 WL 5822595, at *3 (consent decree at issue defining "competent and reliable scientific evidence" in the same manner as defined in the FTC Guidance); *Basic Rsch.*, 2014 WL 12596497, at *9 (Decision and Order at issue defining "competent and reliable scientific evidence" in the same manner as the FTC Guidance); *Garden of Life*, 516 Fed. App'x at 854 (order at issue defining "competent and reliable scientific evidence" in the same manner as the FTC Guidance).

Second, *Bayer, Basic Research*, and *Garden of Life* all reviewed and analyzed what "competent and reliable scientific evidence" means specifically in the context of structure/function claims for dietary supplement products. Each of these courts determined that the FTC Guidance *does not require RCTs at all*, let alone the heightened drug-level RCT Plaintiffs argue should be applied in this action. *See Bayer*, 2015 WL 5822595 at *3-4, *14-19 (observing that the FTC Guidance "makes clear" the substantiation standard for dietary supplements "is not the drug standard;" that "[r]andomized clinical trials are not required" and rejecting the FTC's attempt to impose a "higher-level" of substantiation than required by the FTC Guidance); *Basic Rsch.*, 2014 WL 12596497, at *10-11 (rejecting the FTC's heightened standard and awarding summary judgment because the "FTC failed to apply the correct standard" when evaluating dietary supplement substantiation); *Garden of Life*, 516 Fed. App'x at 856 (rejecting the FTC's attempt to "require the Court to read additional requirements into" the competent and reliable scientific evidence standard.)

Third, Plaintiffs are correct in both of their assertions that the orders at issue in *Bayer, Basic Research*, and *Garden of Life* did not "expressly mention RCTs" and that this "Court is not being asked to interpret a prior order." (Opp. at 11.) That is exactly the point. There is no prior administrative order or consent decree at issue in this action that would define "competent and reliable scientific evidence" in a manner differently than how it is defined in the FTC Guidance. Nowhere in the FTC Guidance is an RCT required, let alone a drug level RCT. (Graham Decl. Ex. F, FTC Guidance at 9—18.) This Court should reject Plaintiffs' attempt to hold Defendants to a higher substantiation standard that is not articulated anywhere except in Plaintiffs' discovery responses and their Opposition brief in this Action. That is exactly what the courts in *Bayer, Basic Research* and *Garden of Life* did when faced with this issue.

Fourth, Plaintiffs' Opposition ignores that *Basic Research* granted ***summary judgment*** in favor of the defendant because the FTC's expert, as here, failed to apply the correct competent and reliable scientific evidence standard. 2014 WL 12596497, at *10-11. Indeed, the court noted that "the FTC must do more than present an expert who simply disagrees with the scientific literature upon which [the defendant] relied. The FTC must present evidence that shows how" such research does not comply with the competent and reliable scientific evidence standard. *Id.* at *10. Here, Plaintiffs cannot show that Defendants did not comply with the FTC Guidance; indeed, none of Plaintiffs' experts reviewed or were even aware of the FTC Guidance *or* the "competent and reliable scientific evidence" standard as it applies to dietary supplement structure/function claims when they rendered their opinions in this case. (CSOF ¶¶ 124—130.) While Plaintiffs contend that their expert, Dr. Sano, "determined that evidence from an RCT is required to establish the efficacy of Prevagen for memory and other cognitive benefits in humans" (Opp. at 10), Dr. Sano testified that she was not at all familiar with the FTC Guidance and was also unfamiliar with the

"competent and reliable scientific evidence" standard that applies to dietary supplements; and she did not offer any opinion (nor could she) with respect to any aspect of Prevagen's marketing. (CSOF ¶¶ 126, 129, 131, 135.) Her opinion, therefore, is at best irrelevant and at worst devastatingly unreliable in that it is not tethered to the issues central to this action (in addition to being premised upon faulty hypotheticals).

2. Defendants Possess Substantiation For Any "Clinically Shown" Claim

Plaintiffs' argument that a subset of the Challenged Claims (those that assert that Prevagen is "clinically shown" to have a beneficial effect) requires a drug-level RCT also misses the mark. (Opp. at 6—9.) Plaintiffs argue, without any record evidence, that the "net impression" of this subset of advertisements "*clearly communicated to consumers* that Prevagen's benefits were supported by clinical evidence, *specifically an RCT*." (Opp. at 8) (emphasis added.) But Plaintiffs offer no evidence of any consumer's perception to establish what was "clearly communicated" to consumers or the "net impression" of any advertisement on a consumer. It is pure *ipse dixit*. None of Plaintiffs' experts are experts in consumer perception, and none of them even reviewed any marketing for Prevagen. (CSOF ¶¶ 131—136.)[5] Plaintiffs simply do not (and cannot) point to any evidence suggesting that consumers interpret the phrase "clinically shown" as suggesting that the claims are established through a drug-level (or higher) RCT. *Id.* In fact, Plaintiffs themselves have asserted that the term "clinical" is "vague and ambiguous." (CSOF ¶ 89.)[6] Accordingly, Plaintiffs' own cited authority establish that they should have, but did not, obtain evidence concerning how consumers perceive this subset of Challenged Claims. *See FTC v. Alcoholism*

[5] While Plaintiffs purported to "contest" these facts, their responses concede that their experts did not review any of Prevagen's marketing material, and that their experts did not offer any opinion on consumers' impression of the Challenged Claims. (CSOF ¶¶ 131—136.)

[6] Elsewhere, Plaintiffs also claim that "RCT" is vague and ambiguous. (CSOF ¶ 118.)

Cure Corp. No. 3:10-cv-266-34JBT, 2011 WL 13137951, at *25 (M.D. Fla. Sept. 16, 2011) ("if an advertisement implies a claim, the court need not conclude that the advertisement makes such a representation without evidence of consumer perception"); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) ("In this case, the FTC has not presented any evidence of what claims consumers perceived the advertisements to make; accordingly, any claims that the FTC contends that the advertisements make must be clear and conspicuous from the face of the advertisements"). To the extent Plaintiffs intend to argue the relevance of consumer perception in connection with the Challenged Claims, their lack of evidence on this issue, despite lengthy and extensive discovery, should be fatal to this argument.

In any event, as this Court has previously found and as Plaintiffs admit in their Complaint (Compl. ¶ 28), Quincy *did* conduct an RCT—the Madison Memory Study—a study that substantiates all of the Challenged Claims in accordance with the FTC Guidance, including any with the words "clinically shown." *FTC v. Quincy Bioscience Holding Company, Inc*., 272 F. Supp. 3d 547, 553 (S.D.N.Y. 2017) ("It is common ground that the Madison Memory Study followed normal, well-accepted procedures, conducted a 'gold standard' double blind, placebo controlled human clinical study using objective outcome measures of human cognitive function"). This Court further found that the Madison Memory Study showed a "statistically significant difference between the groups in the AD 0-1 and AD 0-2 subgroups." *Id*. In addition to the Madison Memory Study, Quincy also possesses other significant "clinical," animal, and *in vitro* evidence, all of which substantiates the advertising for the Challenged Claims.

3. Plaintiffs' Cases Are Inapposite Because They Analyze Substantiation For Disease Claims Rather Than Structure/Function Claims

The cases Plaintiffs cite do nothing to bolster their argument that Quincy lacks adequate substantiation for the Challenged Claims because those cases analyze whether dietary supplement *disease claims* are adequately substantiated.

For example, in *Pom Wonderful, LLC v. FTC*, the defendant marketed various *disease* claims, including that its fruit juice could "treat, prevent, or reduce the risk of . . . heart disease, prostate cancer, and erectile dysfunction," help prevent "heart disease, stroke, Alzheimer's, even cancer," could lead to "improved blood flow to the heart," a "decrease in arterial plaque," and could "lower[] blood pressure in patients with hypertension." 777 F.3d 478, 483, 493-94 (D.C. Cir. 2015). In contrast, here, Plaintiffs do not allege in their Complaint or argue in their Opposition that Defendants made any *disease* claims that warrant the higher substantiation standard applied in *Pom Wonderful*.[7] Rather, the record is clear that Quincy made "*structure/function*" claims[8] that are subject to the *less stringent*, and flexible substantiation standard set forth in the Guidance.

Moreover, despite Pom Wonderful's history of making deceptive *disease* marketing statements, the court in *Pom Wonderful* rejected the FTC's attempt to mandate "two RCTs as an across-the-board requirement for any disease claim." *Id.* at 502. The Court found that "[i]f there

[7] In their Counterstatement of Facts, Plaintiffs cite to a 2012 warning letter that the FDA issued to Mark Underwood as President of Quincy Bioscience Manufacturing, Inc. alleging that Prevagen Products were being promoted for conditions that caused these products to be drugs under the FDCA. (CSOF ¶¶ 11, 16, 109.) This is entirely inconsistent with the position taken in Plaintiffs' Opposition that FDA laws and regulations are inapplicable to this action. (Opp. at 17.) In any event, the allegations contained in the warning letter are just that—allegations. They have never been proven nor have they been the subject of any FDA enforcement activity. In fact, in 2018, the FDA issued a letter closing the matter. Plaintiffs admitted they were not even aware of the closing letter until years into this litigation. (Graham Decl. Ex. EE at Response 100; Graham Reply Decl. Ex. QQ.)

[8] Structure/Function claims describe the role of a nutrient or ingredient intended to affect the structure or function in in humans, provided such claims are not disease claims. (Graham Decl. Ex. J at 2.) Such claims are not subject to FDA pre-authorization and a marketer's ability to make structure/function claims "is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated." (Graham Decl. Ex. F at n.3.)

is a categorical bar against claims about the disease-related benefits of a food product or dietary supplement in the absence of two RCTs, consumers may be denied useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease." *Id.* The court further noted that in most cases "over the past decade," the FTC has required only "competent and reliable scientific evidence," not necessarily RCTs, "let alone two RCTs, to substantiate disease claims akin to those made by petitioners." *Id.* at 504.

Further, *Nat'l Urological Grp., Inc.*, confirms that the FTC Guidance is the appropriate standard for dietary supplement manufacturers to follow regarding substantiation of their marketing claims. 645 F. Supp. 2d at186-87 (N.D. Ga. 2008) (noting that the FTC's "[c]ompetent and reliable scientific evidence" standard has been defined in "guidelines promulgated by the FTC" and discussing FTC Guidance). In that case, the court held that "[t]he fact that different scientific evidence is required from different claims impacting different products does not mean that the FTC can enforce its act arbitrarily; instead it simply means that different claims require different substantiation." *Id.* at 1187. Here, where the FTC Guidance controls, Plaintiffs must abide by the instructions set forth therein.

Other cases Plaintiffs cite involve inapposite scenarios where the defendant disseminated *disease* claims with little to no supporting substantiation. For example, in *FTC v. Coorga Nutraceuticals*, cited throughout Plaintiffs' Opposition, the defendants advertised a purported "cure" to reverse the graying of hair, but had no medical or scientific support for the claims, warranting summary judgment for the FTC. 201 F. Supp. 3d 1300, 1314 (D. Wyo. 2016). Similarly, in *FTC v. Roca Labs, Inc.*, at the time of dissemination, the defendants had *no* scientific studies at all to support the claim that a weight-loss product was "scientifically proven to have a ninety-percent success rate in forcing users to eat half their usual food intake and cause substantial

weight loss[.]" 345 F. Supp. 3d 1375, 1388 (M.D. Fla. 2018). The court did not find that the lack of an RCT was dispositive, but rather, was "*one piece* of evidence," where the defendants "failed to produce *any* competent and reliable scientific evidence to substantiate their claims." *Id.* at 1387 (emphasis added). *See also FTC v. NPB Advert., Inc.*, 218 F. Supp. 3d 1352, 1357-60 (M.D. Fla. 2016) (the defendants relied upon a single study with a sample size of sixteen people that was withdrawn by the author shortly after publication to support a claim that a green-coffee extract product could lead to "losing twenty pounds in four weeks"); *Alcoholism Cure Corp.*, 2011 WL 13137951, at *1, 39) (finding that marketing claims to permanently cure alcoholism were not adequately substantiated by two articles that did not even reference the supplement products being promoted). Those cases are simply irrelevant here given that Defendants have produced a substantial corpus of scientific evidence to support the Challenged Claims—evidence that is consistent with the FTC Guidance and acceptable to Defendants' experts in various scientific fields including internal medicine, nutrition, neuroscience, dietary supplement substantiation, epidemiology and biostatistics. The fact that Plaintiffs do not like that evidence is insufficient to create a triable issue of fact.

Finally, Plaintiffs' citation to *Daniel Chapter One v. FTC* is also irrelevant. In that case, the defendant sought judicial review of an FTC cease and desist order and argued it was exempt from FTC regulation due to its "formal legal status as a religious 'corporation sole' under Washington law." 405 Fed. App'x 505, 506 (D.C. Cir. 2010). Without addressing the substance of the defendant's advertisements or claims, the court held the FTC properly exercised its jurisdiction and did not exceed its statutory authority by issuing an order to cease and desist certain practices. *Id.* That case has no bearing on Plaintiffs' claims in this Action.

C. Plaintiffs' "Contested" Facts Are Based On Unsupported Assumptions Contradicted By The Evidence

Plaintiffs admit on the first page of their Opposition that Defendants conducted an RCT—the Madison Memory Study. (Opp. at 1.) Thus, contrary to Plaintiffs' contention, the parties' disagreement over whether an RCT is required does not create a genuine issue of fact precluding summary judgment. (*Id.* at 19—21.) And while Plaintiffs contend that the Madison Memory Study was "flawed," the so-called flaws relating to the conduct, design and implementation of the Madison Memory Study are supported only by Plaintiffs' experts' assumptions and speculation[9], and are contradicted by the actual evidence in the record.

In this Circuit (and elsewhere), "expert testimony without . . . a factual foundation cannot defeat a motion for summary judgment." *Virgin Atlantic Airways Ltd. v. British Airways PLC*, 69 F. Supp. 2d 571, 579 (S.D.N.Y. 1999), *aff'd* 257 F.3d 256 (2d Cir. 2001) (internal citations omitted). As this Court and courts around the country have long held, "the use of unreliable and unfounded expert testimony . . . is insufficient to defeat" a defendant's summary judgment motion, including where an expert provides "no supporting facts to sustain" his or her conclusions. *Cummiskey v. Chandris, S.A.*, 719 F. Supp. 1183, 1190 (S.D.N.Y. 1989), *aff'd* 895 F.2d 107 (2d Cir. 1990); *see also Standish v. Jackson Hole Mountain Resort Corp.*, 997 F.3d 1095, 1106 n.8 (10th Cir. 2021) ("the mere existence of a contrary expert opinion—particularly a conclusory expert opinion—does not preclude summary judgment"); *Evers v. Gen. Motors Corp.*, 770 F.2d 984, 986 (11th Cir. 1985) ("a party may not avoid summary judgment solely on the basis of an expert's opinion that fails to provide specific facts from the record to support its conclusory allegations"); *New York State Ophthalmological Soc. v. Bowen*, 854 F.2d 1379, 1391 (D.C. Cir.

[9] None of Plaintiffs' experts have conducted any research on Prevagen or apoaequorin. (CSOF ¶ 94) (Plaintiffs objected and offered legal argument in response to this fact, but offered no refuting evidence.)

1988) (same); *Rardon v. Holland*, 279 F. Supp. 3d 93, 97 (D.D.C. 2017) ("a party cannot create a fact issue to avoid summary judgment by offering an expert opinion that is not supported by a proper foundation"); *Basic Rsch.*, 2014 WL 12596497, at *10 (granting summary judgment where expert applied the incorrect standard with respect to dietary supplement).

That is exactly what Plaintiffs attempt to do here, and their efforts to conjure up non-existent disputed issues of fact through unsupported expert opinion should be rejected.

1. There Are No Genuine Issues of Fact Regarding the Design of the Madison Memory Study

Plaintiffs argue that the parties' experts disagree over certain aspects of the Madison Memory Study's design, including the number of participants enrolled in the Madison Memory Study, whether Defendants administered the AD 8 screening tool in a reliable manner, and whether participants were stratified by AD 8 score before or after randomization. (Opp. at 22.) Even assuming these disputes exist, Plaintiffs have failed to explain why these disagreements are material. They are not.

2. There Are No Genuine Issues of Fact Regarding the Blinding of the Madison Memory Study

Plaintiffs next argue that they disagree with Defendants' contention that the Madison Memory Study was double-blinded because two interim analyses were conducted prior to the study's completion and because study participants were informed of their group assignment after completing the study. (Opp. at 22; Pl. Add'l SOF[10] ¶ 25.) These are simply Plaintiffs' assumptions, and neither is supported by the record. As to the first, Dr. Wittes opined that the existence of two interim analyses means that the Madison Memory Study was not blinded. (Pl.

[10] Citations to Pl. Add'l SOF are to Plaintiffs' Statement of Additional Material Facts in Dispute, beginning at page 69 of Plaintiffs' Response to Defendants' Rule 56.1 Statement and Plaintiffs' Statement of Additional Material Facts in Dispute, Dkt. 256.

Add'l SOF ¶ 25; Graham Reply Decl. Ex. RR, Wittes Tr. 132:17—133:13.) But Dr. Wittes later admitted at her deposition that it is possible to conduct an interim analysis without breaking the blind. (Graham Reply Dec. Ex. RR, Wittes Tr. 134:4-22, 138:13-24.)

As to the second, while Dr. Sano opined that the un-blinding of one participant led to the un-blinding of others in the same "block" of participants (Pl. Add'l SOF ¶ 25), she backed away from this opinion at her deposition and admitted that she was unaware of (1) any participant learning the assignment of another participant; (2) any participant learning of their own assignment prior to completing the study; or (3) any proctor learning which group any participant was in before that participant completed the study. (Graham Reply Decl. Ex. SS, Sano Tr. 88:11—89:1, 103:2-10; *see also* Graham Reply Decl. Ex. RR, Wittes Tr. 131:17—132:16.) Dr. Sano further admitted that she may have *"assumed"* that the randomization was conducted in blocks, which was what informed her original opinion that the study was inadequately blinded. (Graham Reply Decl. Ex. SS, Sano Tr. 111:5—114:6; *see also* 93:15-18 (testifying that she was not able to make a determination as to whether the blinding in the Madison Memory Study was adequate).)

Dr. Wittes' and Dr. Sano's unsupported assumptions about the blinding of the Madison Memory Study are not grounded in the record evidence and do not qualify as disputes of fact which preclude summary judgment.

3. There Are No Genuine Issues of Fact Regarding the Intended Population of the Madison Memory Study

Quincy's President (Mark Underwood) and the Madison Memory Study's Principal Investigator (Kenneth Lerner) both testified that individuals with AD 8 scores between 0 and 2 (i.e., normal, healthy older adults) were the target population for the Madison Memory Study and that Defendants decided to analyze the Madison Memory Study data based on AD8 scores before the study commenced. (SOF ¶¶ 100, 107.) Plaintiffs do not offer any *evidence* to dispute these

facts, and instead argue that their experts "reviewed the study's protocol and concluded that the intended study population consists of the over 200 adults who completed the study." (CSOF ¶¶ 100, 107.) The assumptions and conclusions of Plaintiffs' experts from reading the study's protocol are insufficient to rebut Mr. Underwood and Mr. Lerner's undisputed testimony, especially since it is corroborated by the *undisputed* facts that: (1) AD8 scores between 0 and 2 are "generally considered reflective of normal aging or 'very mild' cognitive impairment—i.e. healthy, older adults" (CSOF ¶ 99); and (2) the protocol for the Madison Memory Study listed a planned sample size of 100 participants, and the study included 100 participants who reported AD8 scores between 0 and 2 (CSOF ¶¶ 103—104).

4. There Are No Genuine Issues of Fact Regarding the Subgroups Analyzed as Part of the Madison Memory Study

Plaintiffs also contend that the planned AD 8 0-1 and 0-2 subgroup analyses were "not pre-specified" and "would be considered *post hoc* statistical analyses that cannot support conclusions about a product's efficacy." (Opp. at 24.) But, even assuming that a "post hoc" analysis is somehow per se invalid (it is not, as Defendants' experts made clear), as discussed in the preceding section, Plaintiffs cite no evidence to support their theory that the analyses were not pre-specified and the record evidence makes clear those groups were the intended analyses from the outset of the Madison Memory Study. (CSOF ¶¶ 99, 100, 103—104, 107.)

Plaintiffs also failed to amass evidence supporting their theory that the AD 8 0-1 and 0-2 subgroup analyses were, in fact, "post hoc." It is undisputed that a "post hoc" analysis is one that is conducted "after whoever is doing the analysis looks at the data." (CSOF ¶ 140.) But Dr. Sano and Dr. Wittes both admitted at their depositions that they did not know when or in what order the

0-1 and 0-2 analyses were planned or conducted. (CSOF ¶¶ 141[11]—142[12].) Thus, even assuming the Parties' experts disagree over the propriety of post hoc subgroup analyses (CSOF ¶ 143), Plaintiffs have failed to raise a question of fact as to whether the 0-1 and 0-2 subgroup analyses were, in fact, post hoc and therefore the alleged disagreement is immaterial and does not preclude summary judgment. Despite several years of litigation including intensive fact and expert discovery, as this Court previously found, Plaintiffs' challenge "never proceeds beyond the theoretical." *Quincy Bioscience*, 272 F. Supp. 3d at 553 (citing *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 168 (2d Cir. 2016)).

5. There Are No Genuine Issues of Fact Regarding Whether the Results of the Madison Memory Study are "Statistically Significant"

Plaintiffs and their experts (Drs. Sano and Wittes) argue that research results must be "statistically significant" in order to constitute competent and reliable scientific evidence (they were). (Opp. at 25—26.) But this is not the prevailing view of experts in the field of biostatistics. Indeed, Defendants' biostatistics expert, Dr. Wei, demonstrated that this outdated and arbitrary approach has been strongly criticized by experts in the field of statistics and by the preeminent American Statistical Association ("ASA") (of which Dr. Wittes is a member). (Graham Decl. Ex. Z, Wei Report ¶¶ 20-22 and Appendix C; Graham Reply Decl. Ex. RR, Wittes Tr. at 146:19-22.) As the ASA advises, "[s]cientific conclusions and business or policy decisions should not be based only on whether a p-value passes a specific threshold." (Graham Decl. Ex. Z, Wei Report ¶¶ 20—22 and Appendix C.) Contrary to Plaintiffs' characterization of Dr. Wittes' report, she testified at her deposition that, "in general," she actually "agree[s] [] with the sentiments expressed in that

[11] Plaintiffs' response to SOF ¶ 141 is consistent with Defendants' proffered fact and should be deemed admitted.

[12] Because Dr. Wittes' admissions at her deposition undermined this paragraph of her report (SOF ¶ 142), Defendants' proffered fact should be deemed admitted.

paper." (Graham Reply Decl. Ex. RR, Wittes Tr. 146:23—147:9.) Thus, to the extent Plaintiffs' experts disagree at all with Dr. Wei and the ASA, that disagreement fails to raise an issue of fact given that the FTC Guidance looks to experts in the relevant field, which the ASA undoubtedly is.[13]

In any event, the purported disagreement is immaterial because the Madison Memory Study did report statistically significant results (using the p-value of 0.05 proffered by Plaintiffs' own experts) for participants scoring between a 0 and 2 on the AD 8 scale. (SOF ¶¶ 109—111.) Participants in the 0-1 subgroup reportedly experienced statistically significant improvement as compared to the placebo group on three Cogstate tasks (GMR, DET, and OCL) and outperformed the placebo group on four additional tasks. (SOF ¶ 111.) Similarly, participants in the 0-2 subgroup reportedly experienced statistically significant improvement as compared to the placebo group on three Cogstate tasks (GML, OCL, and IDN). (SOF ¶ 110.) Moreover, the placebo group did not show any statistically significant improvement as compared to the treatment group on any of the Cogstate tasks in the AD8 0-1 or 0-2 subgroups. (SOF ¶ 112.)

Plaintiffs do not contest these results, but instead argue that they are not truly "statistically significant" because the subgroup analyses were post hoc and therefore required a statistical correction. But, as discussed in the preceding section, there is no basis in the record for Plaintiffs' experts' *assumptions* that these analyses were post hoc, and therefore no basis to require any statistical correction. (CSOF ¶¶ 109—112.)

[13] Plaintiffs also admit that they have not issued any regulation or guidance requiring statistical significance in the entire study population to constitute adequate substantiation. (CSOF ¶ 78.)

6. There Are No Genuine Issues of Fact Regarding Whether the Madison Memory Study Results are "Clinically Meaningful"

Finally, Plaintiffs argue that the Parties disagree over whether the Madison Memory Study's results are clinically meaningful. (Opp. at 26.) While Dr. Sano opined in her report that they are not (Pl. Add'l SOF ¶ 43), she subsequently admitted at her deposition that she believed it was "questionable" whether the results of just *one* of the Cogstate tests was clinically meaningful, was "not sure" that she "evaluated them all to that degree" and was "not prepared to say one way or the other" whether the remaining positive results were clinically meaningful. (Graham Reply Decl. Ex. SS, Sano Tr. 138:16—140:17.) Dr. Sano's equivocal testimony therefore does not raise a genuine issue of fact precluding summary judgment.[14]

7. There Are No Genuine Issues of Fact Regarding the Remainder of Defendants' Substantiation

The Madison Memory Study, by itself, is sufficient to substantiate the Challenged Claims. Thus, any purported disputed issues of fact with respect to Defendants' animal, *in vitro*, open label or vitamin D studies have no legal relevance and cannot preclude summary judgment. But even if they were relevant, Plaintiffs' expert's opinions as to these additional studies are unsupported by the evidence.

The FTC Guidance expressly provides that animal, *in vitro* and open label research will be considered under the FTC's "totality of the evidence" approach. Plaintiffs' expert, Dr. Sano, however, dismissed this research out of hand, opining that (1) placebo-controlled "[t]esting on humans is necessary," (2) results from animal studies "cannot be directly extrapolated from an

[14] In a desperate attempt to create issues of fact, Plaintiffs even contest whether or not certain results from the Madison Memory Study were published in a peer-reviewed journal. (CSOF ¶ 115.) Their response that this fact "misstates the quality of the *Advances in Mind Body Medicine* journal" is non-responsive and fails to raise an issue of fact. Even if Plaintiffs are correct that the journal has a "low impact factor," which Plaintiffs contend "suggest[s] it does not have a strong reputation among scientists," that does not refute the proffered fact that the article was published in a peer-reviewed journal, which *strengthens* its reliability under the FTC Guidance. (Graham Decl. Ex. F, Guidance at 12.)

animal model to humans," and (3) *in vitro* studies "are not necessarily predictive of what will happen in the human body and are not adequate evidence of efficacy absent confirmation in human studies." (Graham Decl. Ex. T, Sano Report ¶¶ 29, 41.) She specifically declined to report on these studies "because they are not considered sufficient competent and reliable scientific evidence of an effect in humans." (Graham Decl. Ex. T, Sano Report ¶ 42.) And while Dr. Sano conducted a cursory review of this material in her rebuttal report (Soberats Decl. Ex. B, Sano Rebuttal Report ¶¶ 3, 14—19), she admitted at her deposition that she had not "considered whether the animal studies performed by Quincy would be relevant to making a determination of Prevagen's efficacy in humans," that she was "not commenting on the animal studies," that she did not "place any weight" on animal studies in determining efficacy in humans," and that open-label studies in humans are not relevant to efficacy determinations. (Graham Reply Decl. Ex. SS, Sano Tr. 78:23—79:6; 81:8-18, 83:5—84:6.) In short, Dr. Sano's opinions are directly contrary to the FTC's own Guidance, and she failed to consider the scientific evidence that Quincy developed—even though that evidence is clearly allowed under the FTC Guidance. This is compounded by the fact that Dr. Sano was entirely unfamiliar with the FTC Guidance and the relevant "competent and reliable scientific evidence" standard. Dr. Sano's opinion fails to raise a genuine issue of fact.

Plaintiffs cite *FTC v. SlimAmerica, Inc.* and *Western Sugar Coop. v. Archer-Daniels-Midland Co.* (Opp. at 27) for the unremarkable proposition that animal and *in vitro* studies, standing alone, are insufficient to substantiate marketing claims. These cases are inapposite for at least two reasons. First, Quincy is not relying solely on its animal and *in vitro* research. Rather, those studies provide *additional* evidence that increases the reliability of the Madison Memory Study. Second, Defendants' expert Dr. Mindy Kurzer opined that Quincy's canine studies (the results of which were published in a peer-reviewed journal) are of particular relevance here

because cognitive dysfunction in dogs is thought to provide a natural animal model for cognitive dysfunction in humans. (SOF ¶ 88.) Dr. Sano, who purports to be an expert in cognition, had no basis to dispute this opinion from Dr. Kurzer and admitted that she did not even recall reviewing the references that Dr. Kurzer cited in support of her opinion. (Graham Reply Dec. Ex. SS, Sano Tr. 77:13—78:3.) Thus, unlike in *SlimAmerica* and *Western Sugar*, where the courts questioned the extrapolation of animal studies to humans, Defendants have offered—and Plaintiffs failed to rebut—evidence supporting such a conclusion in this case.

In short, speculative legal argument and uninformed expert opinion untethered to the factual record is insufficient to defeat Defendants' summary judgment motion, particularly where none of Plaintiffs' experts formed their opinions using the governing "competent and reliable scientific evidence" standard as set forth in the FTC Guidance.

D. Plaintiffs Failed To Provide Any Evidence That The Challenged Claims Are Likely To Mislead Consumers

Defendants' Motion established that Plaintiffs have failed to elicit *any* evidence that the Challenged Claims are likely to mislead consumers. (Mot. at 31.) In response, Plaintiffs argue that the "net impression Defendants conveyed to consumers was that their memory and cognitive function claims were supported by an RCT," but that the RCT was "flawed" and cannot support Quincy's marketing claims. (Opp. at 2.) Plaintiffs further argue that the advertising disclaimer agreed to as part of the *Collins* Settlement (the "Qualifier") "fails to alter the deceptive net impression of Defendants' ads." (Opp. at 33.) Despite numerous opportunities, Plaintiffs have failed to offer any evidence to support these arguments.

It is undisputed that Quincy conducted an RCT (Opp. at 1; Compl. ¶ 28) and so the alleged "clinically shown" advertising claims cannot be literally false. Moreover, "where the language of an advertisement is 'susceptible to more than one reasonable interpretation, the advertisement

cannot be literally false.'" *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009). In the context of a consumer fraud claim, differing scientific opinions necessarily mean that an advertising claim cannot be misleading. *See In re GNC Corp.*, 789 F.3d 505, 515 (4th Cir. 2015) ("In sum, we hold that in order to state a false advertising claim on a theory that representations have been proven to be false, plaintiffs must allege that all reasonable experts in the field agree that the representations are false. If plaintiffs cannot do so because the scientific evidence is equivocal, they have failed to plead that the representations based on this disputed scientific evidence are false."). And where an advertisement is not literally false, a private plaintiff "may bring an implied claim on the ground that the advertisement although literally true is nonetheless misleading, but [they] must offer consumer data or other extrinsic evidence to show that the audience to which the advertisement is directed is in fact misled by the advertisement." *Stokely-Van Camp, Inc.*, 646 F. Supp. 2d at 525. *Id.* As discussed above, the FTC's own cases demonstrate that they should have set forth consumer perception evidence if they wanted to establish their theory of what "clinically shown" means is the prevailing theory. *See Alcoholism Cure Corp*, 2011 WL 13137951, at *25; *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d at 1189. They did not do so.

The same rationale applies here. In fact, Plaintiffs assert that the term "clinical" is "vague and ambiguous" (CSOF ¶ 89), triggering their obligation to provide evidence of how consumers interpreted this vague and ambiguous term. Moreover, Plaintiffs were on notice that the Court considered this to be a significant issue when it originally dismissed Plaintiffs' Complaint nearly five years ago. "Thus, the complaint fails to show that reliance upon the subgroup data 'is likely to mislead consumers acting reasonably under the circumstances,' as is necessary to state its claim." *Quincy Bioscience*, 272 F. Supp. 3d at 553 (citing *FTC v. LeadClick Media, LLC*, 838

F.3d 158, 168 (2d Cir. 2016)). Plaintiffs should have known that they were required to produce evidence of consumer perception if they intended to argue that the Challenged Claims were likely to mislead consumers acting reasonably under the circumstances. They failed to do so, warranting summary judgment in Defendants' favor.

In an attempt to side-step this requirement, Plaintiffs argue that Quincy "lack[s] a reasonable basis" for the Challenged Claims, rendering them "deceptive as a matter of law," and that "Plaintiffs need not provide evidence of actual deception to establish the elements of their case." (Opp. at 36.) Plaintiffs' argument misses the point. Defendants are not arguing that Plaintiffs need to provide "evidence of actual deception," but they were obligated to come forward with evidence as to how consumers perceived what Plaintiffs now admit to be vague and ambiguous advertising. In any event, the cases they cite in support are readily distinguishable.

In *FTC v. Direct Marketing Concepts, Inc.*, for example, the defendant made express disease claims, arguing its products could cure "literally every disease, from cancer to Parkinson's to obesity." 624 F.3d 1 (1st Cir. 2010). The court found that the defendant lacked a reasonable basis for its marketing claims because it failed to offer *any* substantiation for the claim that the products "can prevent, treat, or cure cancer, heart disease, or diabetes," relying solely on "extrapolations, distortions, and sometimes, seemingly, utter fabrications." *Id.* at *9-11. Notably, the court stated that "a double-blind study is not necessarily required" to substantiate the claims that the products cure cancer. *Id.* at *9. Defendants, in contrast, have offered a wealth of scientific substantiation, including the Madison Memory Study, animal studies, *in vitro* studies, open label studies on apoaequorin, as well as additional research on vitamin D.

In *FTC v. Commerce Planet, Inc.*, the FTC actually retained an expert who reviewed the allegedly misleading website and opined that "most users" would have been misled. 878 F. Supp.

2d 1048, 1054 (C.D. Cal. 2012), *aff'd in part*, 642 Fed. App'x 680 (9th Cir. 2016), *and aff'd in part, vacated in part, remanded*, 815 F.3d 593 (9th Cir. 2016). Plaintiffs here did not retain any experts to opine on Defendants' marketing; in fact, each of Plaintiffs' retained experts admitted at their depositions that they did not review a single piece of Prevagen's marketing. (CSOF ¶ 131.)[15]

And *Trans World Accounts, Inc. v. FTC*, is procedurally inapt, as it involved federal court review of a decision rendered in an administrative proceeding commenced under Section 5 of the FTC Act. 594 F.2d 212, 214 (9th Cir. 1979). In a Section 5 appeal, "[t]he scope of appellate review of factual findings made by the FTC is narrow," and such facts, "if supported by evidence, shall be conclusive.'" *Id*. at 215.

Plaintiffs have raised no issue of material fact on consumer perception and summary judgment should be granted in favor of Quincy.

E. Plaintiffs Failed To Support Their Net Impression Argument With Any Evidence

Plaintiffs fail to offer any evidence in support of their argument that the *Collins* Qualifier "fails to alter the deceptive net impression of Defendants' ads." (Opp. at 33—36.) In fact, they failed to offer any evidence whatsoever regarding consumer perception of the *Collins* Qualifier, despite Second Circuit precedent requiring that where, as here, a plaintiff's theory of recovery is premised upon a claim of implied falsehood, that plaintiff "must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers." *Johnson & Johnson * Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992). Plaintiffs' failure of proof on this point warrants summary judgment in Defendants' favor.

[15] Plaintiffs' response to this fact contains legal argument and does not specifically refute Defendants' assertion that Plaintiffs' experts did not review any marketing material for Prevagen. The fact should therefore be deemed admitted.

In each of Plaintiffs' cases, the FTC satisfied its burden of proof by offering extrinsic evidence of consumer perception. In *FTC v. Cyberspace.com, LLC*, for example, the defendant mailed checks to existing customers for $3.50 that were, in reality, solicitation checks for an internet service with a monthly recurring charge. 453 F.3d 1196, 1199 (9th Cir. 2006). The back of the check contained a "small-print disclosure[] revealing that cashing or depositing the check would constitute agreement to pay a monthly fee for internet access, but the front of the check . . . contained no such disclosure[]." *Id.* at 1198. The FTC proffered evidence of consumer perception, including a consumer research survey demonstrating a lack of understanding of the service, evidence that less than 1% of individuals billed for the service actually logged on to use it, and consumer complaints, all of which supported the court's finding that the disclaimer was insufficient to remedy the misleading solicitation. *Id.* at 1198-201.

Similarly, in *Independent Directory Corp. v. FTC*, the FTC proffered testimony from "a fair number" of consumers "as to the actual deceptive effect" of the challenged solicitation practices. 188 F.2d 468, 470 (2d Cir. 1951). *See also FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 294, 306-07 (S.D.N.Y. 2008) (the FTC submitted sworn declarations from consumers to support their net impression argument); *FTC. v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 519, 532 (S.D.N.Y. 2000) (the FTC offered evidence that various state agencies had already found the defendant's business to be a pyramid scheme, and also retained an expert witness who testified that only a small number of consumers who participated in the multi-level marketing scheme earned the promised "free vehicles" or otherwise earned more money than they paid to participate in the program).[16]

[16] Plaintiffs' final case, *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489 (1st Cir. 1989), is procedurally inapposite, as it resolved a petition for review of an FTC administrative cease and desist order. In such cases, the FTC findings "with respect to what representations are made in advertisements are factual" and the court was required to "accept the Commission's findings of fact if they are supported by 'such relevant evidence as a reasonable mind might accept

Unlike in those cases, Plaintiffs have offered no expert testimony regarding consumer perception of the *Collins* Qualifier, no consumer research survey, and no consumer complaints that any consumers were misled or of any alleged deception. Indeed, here, it is undisputed that Plaintiffs submitted no extrinsic evidence *at all*. (CSOF ¶¶ 132—134.)[17] In fact, the only extrinsic evidence in the record relating to the *Collins* Qualifier was proffered by Defendants—and it established that a federal court has already established that the Qualifier[18] is "fair, reasonable, and adequate." (CSOF ¶ 41.)[19] In short, Plaintiffs argue that this Could should accept their view of the Qualifier (that it is "insufficiently prominent") based on nothing more than their own their own say-so. This failure of proof warrants summary judgment in Quincy's favor.[20]

III. PLAINTIFFS' ATTEMPT TO IMPOSE A HEIGHTENED SUBSTANTIATION STANDARD VIOLATES DUE PROCESS

Plaintiffs' request for a higher substantiation requirement than the one set forth in the FTC Guidance is all the more concerning because it would retroactively impose a revised interpretation of federal law in violation of Quincy's due process rights. (Mot. at 31—34 (citing *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) and *Upton v. SEC*, 75 F.3d 92, 95 (2d Cir. 1996)).)

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as adequate to support a conclusion.'" *Id.* at 1496-97. This substantial level of deference accorded to the FTC is not appropriate in district court litigation when it has the burden of proof.

[17] Plaintiffs purport to contest these facts on relevancy grounds only. They should be deemed admitted.

[18] Plaintiffs assert that Quincy is still airing a handful of ads without the Qualifier. (Opp. at 32—33.) Upon receiving Plaintiffs' assertions, Quincy immediately investigated the issue and found that, due to an oversight and a production error, certain limited videos inadvertently aired without the Qualifier for a limited time period. (Olson Reply Decl. ¶¶ 4-6.) Upon being notified of the oversight, it was corrected. (*Id.* ¶ 7.)

[19] Plaintiffs purport to contest this fact on relevancy grounds only. It should be deemed admitted.

[20] Plaintiffs' alternative argument that the *Collins* Qualifier "improperly represents that Defendants' flawed analysis of subgroups from the Madison Memory Study supports the Challenged Claims" (Opp. at 34—35) fails for the same reasons discussed above, namely that Plaintiffs have failed to offer any evidence that the referenced subgroup analyses were, in fact, *post hoc.* (*See* Section II.C.3-4, *supra*.)

In fact, the FTC Guidance—which Plaintiffs admit is intended to *help* marketers understand how FTC law applies to the advertising of dietary supplements (CSOF ¶ 63)—states that "well-controlled human clinical studies are the *most reliable* form of evidence." (Graham Decl. Ex. F, Guidance at 10 (emphasis added).) It does *not* state that well-controlled human clinical studies are the *only* acceptable form of evidence, nor does it impose the drug-level RCT study design and analysis that Plaintiffs require here. Rather, the FTC Guidance states that animal and *in vitro* studies, which Plaintiffs and their experts rejected out of hand (*see* Section II.C.7, *supra*), "***will*** also be examined." (Graham Decl. Ex. F, Guidance at 10 (emphasis added).) Plaintiffs' attempt to retroactively apply this heightened standard without prior notice violates Due Process because it would "result in precisely the kind of 'unfair surprise' against which the Supreme Court has long warned." *Christopher* 567 U.S. at 156. This is particularly true for a company like Quincy that spent years (and an enormous amount of money) developing substantiation for the Challenged Claims even before it conducted the Madison Memory Study, and has specifically reviewed, relied upon, and obtained advice from outside counsel regarding the standard set forth in the FTC Guidance to ensure that its marketing claims for Prevagen were adequately substantiated. (CSOF ¶¶ 74—75.)[21]

Plaintiffs do not meaningfully argue otherwise. They fail to address *any* of Defendants' case law (from the Supreme Court and from this Circuit) rejecting governmental efforts to impose standards of conduct that are inconsistent with prior interpretations of applicable rules or regulations. Instead, Plaintiffs attempt to distort the record, arguing that their expert "reviewed the other purported substantiation, including human and animal studies, and found that none of those additional materials supported the claims at issue." (Opp. at 16.) But, as discussed above,

[21] Plaintiffs fail to cite any evidence to refute these proposed facts. They should be deemed admitted.

Dr. Sano did not meaningfully consider Quincy's animal, *in vitro* and open label human studies; she dismissed them outright, which is directly contradictory to the plain terms of the FTC Guidance. (*See* Section II.C.7, *supra.*)[22] Plaintiffs' attempt to substitute Dr. Sano's *personal* belief that animal and *in vitro* studies are irrelevant for the flexible standard in the FTC Guidance that *mandates* consideration of those same types of studies violates Quincy's Due Process rights and should be rejected.

IV. PLAINTIFFS ARE NOT ENTITLED TO INJUNCTIVE RELIEF

A. The FTC Failed To Satisfy Section 13(b)'s Prerequisites for Permanent Injunctive Relief

In *AMG Capital*, the Supreme Court proposed two possible readings of Section 13(b)'s provision for permanent injunctive relief. First, the Supreme Court stated that "the appearance of the words 'permanent injunction' (as a proviso) suggests that those words are directly related to a previously issued preliminary injunction." *AMG*, 141 S. Ct. at 1348. This is the interpretation Defendants call for here. Alternatively, the Supreme Court stated that the same statutory language "might also be read . . . as granting authority for the Commission to go one step beyond the provision and ('in proper cases') dispense with administrative proceedings to seek what the words literally say (namely, an injunction)." *Id.* In posing these two, potential readings of Section 13(b), the Supreme Court has essentially invited future litigants and courts to consider what it deemed to be ambiguous statutory language.

Defendants' position is therefore far from "novel," as Plaintiffs suggest. (Opp. at 42.) It is what the Supreme Court specifically anticipated in *AMG*. And while this portion of the Supreme Court's opinion may be considered dicta, that does not mean it should be ignored. In fact, this

[22] Dr. Sano testified that she did not know whether the Guidance permits consideration of animal studies in determining whether a claim is substantiated by competent and reliable scientific evidence. (Graham Reply Decl. Ex. SS, Sano Tr. 81:19-23.)

Circuit has long held that courts should not "cavalierly disregard" Supreme Court dicta, and that it "must be given considerable weight . . ." *U.S. v. Bell*, 524 F.2d 202, 206 (2d Cir. 1975); *see also Cornwell v. Credit Suisse Group*, 729 F. Supp. 2d 620, 625 (S.D.N.Y. 2010). This is especially true where, as here, the Supreme Court "is providing a construction of a statute to guide the future conduct of inferior courts." *Bell*, 524 F.2d at 206; *Cornwell*, 729 F. Supp. 2d at 625; *DeLaurentis v. Job Shop Technical Servs., Inc*., 914 F. Supp. 57, 63 (E.D.N.Y. 1996) (stating that, in some instances, courts have a duty to be guided by Supreme Court dicta).

But Plaintiffs refuse to acknowledge even the *possibility* of the Supreme Court's first proposed interpretation of the "proper case" language from the *AMG* decision, and instead argue that a "proper case" is one in which the FTC shows that the challenged conduct is ongoing or likely to recur. (Opp. at 43.) But this interpretation would render the "proper cases" proviso completely superfluous in contravention of Supreme Court guidance. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (courts should "give effect, if possible, to every clause and word of a statute").[23] Congress chose to include that language and it should not be ignored.

Instead of confronting this language, Plaintiffs argue that every post-*AMG* court to consider this issue has ruled in favor of the FTC. Be that as it may, it is this Court's duty to read and apply the statute as written. Indeed, for decades prior to the Circuit-split that led to the *AMG* decision, Courts of Appeal and District Courts across the country almost *uniformly* held that the FTC was able to recover monetary relief under Section 13(b). *See AMG*, 141 S. Ct. at 1346-47. But those decisions did not preclude courts (both the Supreme Court and lower courts) from revisiting the

[23] Plaintiffs also overlook that, when Section 13(b) was added to the FTC Act in 1973, *United States v. W. T. Grant Co*. had been on the books for two decades. If Congress intended the "proper case" language to mirror the existing standard for injunctive relief, it would not have needed to include the "proper case" language at all.

statutory language and diverging from the rationale of prior decisions upon a determination that they were wrongly decided.

In *FTC v. Hoyal & Associates*, the only Court of Appeals case Plaintiffs cite on this issue,[24] the Ninth Circuit cited a handful of decades-old, pre-*AMG* decisions for the proposition that the FTC can obtain injunctive relief without initiating administrative proceedings. 859 Fed. App'x 117, 120 (9th Cir. 2021) (citing *FTC v. Evans Prods.*, 775 F.2d 1084, 1086 (9th Cir. 1985) and *FTC v. H. N. Singer, Inc.*, 668 F.2d 1107, 1110 (9th Cir. 1982)). The *Hoyal* decision offers no substantive interpretation of the statutory language or the decision in *AMG*, and simply followed that outdated precedent called into question by *AMG*. *Id.*

Three of the five cited District Court cases were decided by the District of Arizona and followed prior Ninth Circuit precedent. This Court need not do so. Unlike *Hoyal*, the District of Arizona *has* considered the relevant language in *AMG*, and appears to *agree* with Defendants that the Supreme Court was presenting two alternative readings of the statutory language—one that requires the FTC to first obtain a preliminary injunction before seeking a permanent injunction and the other that permits the FTC to dispense with administrative proceedings to seek a permanent injunction in federal court. *FTC v. Elec. Payment Sol. of Am. Inc.*, No. CV-17-02535, 2021 WL 3661138, at *16 (D. Ariz. Aug. 11, 2021). Ultimately, though, the court decided that it could "not ignore Ninth Circuit precedent" (including *Hoyal*, *Evans Products* and *H.N. Singer*) "without a clearer holding of law from the Supreme Court." *Id.* at *16. *See also FTC v. Noland*, No. CV-20-00047, 2021 WL 4127292, at *17 (D. Ariz. Sept. 9, 2021) (holding that *AMG* "overruled existing Ninth Circuit law in one respect" but that prior Ninth Circuit holdings that the FTC can obtain permanent injunctive relief in the absence of administrative proceedings "remain binding on

[24] *Hoyal* is unpublished and "not precedent" under Ninth Circuit Rules of Appellate Procedure (*see* R. 36-3).

district courts within the Ninth Circuit."); *FTC v. SuperTherm Inc.*, No. CV-20-08190, 2021 WL 3419035, at *6 (D. Ariz. Aug. 5, 2021) (same).

In *FTC v. Neora LLC*, the Northern District of Texas similarly explained that *AMG* "made no definitive statement regarding the availability of permanent injunctions vis-à-vis administrative enforcement proceedings, nor any pronouncement as to what constitutes a 'proper' case under 13(b), in which a permanent injunction could be available." 552 F. Supp. 3d 628, 634 (N.D. Tex. 2021). Like the District of Arizona, the *Neora* court was unwilling to reach a result that was inconsistent with pre-*AMG* precedent (including *H. N. Singer* and other cases from the 1980s). *Id.* at 634-36; *see also FTC v. Am. Future Sys., Inc.*, No. 20-CV-2266, 2021 WL 3185777, at *1 (E.D. Pa. July 26, 2021) (relying on pre-*AMG* cases from the Third, Seventh and Ninth Circuits to hold that the FTC can obtain a permanent injunction without seeking preliminary or temporary relief).

Here, Plaintiffs fail to cite (and Defendants have been unable to locate) *any* controlling Second Circuit precedent that would compel this Court to disregard the Supreme Court's dicta in *AMG*.[25] Thus, this Court can—and should—review the statutory language on its own, give "considerable weight" to the Supreme Court's discussion of the issue, and find that Section 13(b)'s provision for permanent injunctive relief in "proper cases" means cases in which the agency has either commenced a contemporaneous administrative proceeding and/or sought preliminary relief at the outset of the federal court litigation.

[25] The only Second Circuit cases cited in connection with Plaintiffs' Section 13(b) arguments are *FTC v. Moses*, 914 F.3d 297 (2d Cir. 2019) and *SEC v. Commonwealth Chem. Sec., Inc.*, 574 F.2d 90 (2d Cir. 1978), but neither support their position. (Opp. at 41 & n. 12.) In *Moses,* the FTC obtained a temporary restraining order at the outset of the litigation and so the issue was not presented to the court. *Moses.* 914 F.3d at 304, 309-310. And *Commonwealth* involved a different statute altogether (the Securities Act). *Commonwealth*, 574 F.2d at 92.

B. Plaintiffs Are Not Entitled To Injunctive Relief Under *W. T. Grant*

Plaintiffs have also failed to establish their right to injunctive relief under *W. T. Grant Co.*. As discussed above and in Defendants' Motion, *W. T. Grant* requires parties seeking an injunction to show "that there exists some cognizable danger of recurrent violation, something more than the mere possibility" that the conduct complained of could be repeated." (Mot. at 41.) Plaintiffs also cite *American Freedom Defense Initiative v. Metropolitan Transportation Authority*, which sets forth a two-pronged test to determine whether a case is moot after the defendant voluntarily discontinues challenged conduct. 815 F.3d 105 (2d Cir. 2016). Under that test, a case will be deemed moot if "(1) it can be said with assurance that 'there is no reasonable expectation' that the alleged violation will recur" and "(2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation." *Id.* Defendants' Motion established, and Plaintiffs failed to dispute, that there is no cognizable danger of recurrent violation and that the circumstances satisfy the two-prong test set forth in *American Freedom Defense Initiative.*[26]

First, there is no reasonable expectation that the alleged violations will recur. Defendants have offered evidence establishing that they stopped disseminating the Challenged Claims in the manner alleged in the Complaint and have no intention of resuming them. (SOF ¶¶ 28—38.) Plaintiffs' response that this evidence constitutes "self-serving statement[s] of Defendants' future intentions regarding advertising" is purely attorney argument that does not raise a triable issue of fact precluding summary judgment. (CSOF ¶¶ 28—38.) Defendants proffered additional evidence that they entered into a nationwide class action settlement agreement, reduced to a final judgment by a federal court, resolving a series of class actions challenging the same marketing claims alleged

[26] Plaintiffs' citation to *American Freedom Defense Initiative* is curious, as the Second Circuit found the two-pronged test to be satisfied and vacated the previously-issued injunction as moot. 815 F.3d at 109-11.

in this Action in which Defendants agreed not to make the challenged marketing claims without including one of two Qualifiers. (SOF ¶¶ 39, 42, 45.)[27] Plaintiffs failed to cite any evidence to dispute these facts, and instead simply argued that they are "irrelevant and immaterial." (CSOF ¶¶ 39, 42, 45.) This is also insufficient to defeat summary judgment.

Defendants' evidence also satisfies the second prong of *American Freedom Defense Initiative*—that interim relief or events have completely and irrevocably eradicated the effects of the alleged violation. Not only have Defendants ceased disseminating the Challenged Claims, every single person who purchased Prevagen in the United States since it became available for sale in 2007 was entitled to obtain monetary relief and were provided with injunctive relief under the *Collins* Settlement. (SOF ¶ 43.) The United States District Court for the Southern District of Florida specifically found the terms of the *Collins* Settlement to be "fair, reasonable and adequate." (SOF ¶ 41.)[28] Again, Plaintiffs fail to contest these facts, and simply argue that they are "irrelevant and material." (CSOF ¶¶ 41, 43.) But Plaintiffs' own case law establishes their relevance, and Plaintiffs' lack of countervailing evidence warrants summary judgment in Defendants' favor.[29]

[27] As discussed above, while Plaintiffs *argue* that the Qualifiers are inadequate to change the deceptive net impression of Defendants' ads" (Opp. at 38), Plaintiffs have offered no evidence to support such a claim. (*See* Section II.D, *supra*.)

[28] Plaintiffs failed to distinguish, or even address, *In re Santa Fe Natural Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.* 288, F. Supp. 3d 1087, 1212, 1233 (D.N.M. 2017) (cited on page 41-42 of Defendants' Motion), which declined to hold a defendant liable for using an advertising disclaimer that had previously been agreed to in a settlement agreement with FDA.

[29] Plaintiffs' citations to *People v. Gen. Elec. Co.*, 302 A.D.2d 314, 316 (1st Dep't 2003), *State v. Midland Equities*, 117 Misc. 2d 203 (Sup. Ct. N.Y. Cnty. 1982), and *People v. Ludwig Bauman & Co.*, 56 Misc. 2d 153 (Sup. Ct. N.Y. Cnty. 1968) are also unavailing, as they each involved truly voluntary cessation that was not accompanied by the assurances provided by a class action settlement agreement reduced to a final judgment. (Opp. at 39.)

V. THE NYAG'S CLAIMS ARE PREEMPTED OR BARRED BY THE SAFE HARBOR PROVISION IN THE GBL

Quincy also established in its Motion that the NYAG's claims are preempted, barred by the GBL's safe harbor provision, or both, and Plaintiffs fail to raise any dispute of fact suggesting otherwise. (Mot. at 43—45.)

As an initial matter, Defendants have not waived their preemption defense. Rule 8(c) of the Federal Rules of Civil Procedure requires defendants to state affirmative defenses "in short and plain terms" to "protect plaintiffs from any unfair surprise." *Colon ex rel. Molina v. BIC USA, Inc.*, 136 F. Supp. 2d 196, 200 (S.D.N.Y. 2000). In *Colon*, this Court found the defendant had not waived a preemption defense in a product liability action where its answer stated that the product at issue "met and/or exceeded the applicable federal and industry standard" because that language put the plaintiff "on notice" of a preemption defense (even though the defendant "did not specifically use the word 'preemption' in its affirmative defense"). *Id.* Here, it is not even a close call. Defendants did more than the defendant in *Colon*, alleging as its Fourteenth Affirmative Defense that it "complied with all federal and state statutes, rules, regulations, or other laws in effect at the time of its alleged conduct and, therefore, is not liable for any wrongdoing alleged in the Complaint." (Dkt. 73 at 10.) The lack of the specific word "preemption" is of no legal relevance; that affirmative defense clearly put the NYAG on notice of Defendants' preemption defense, and any alleged "surprise" expressed by the NYAG as to this defense is unreasonable.[30]

[30] Even if Defendants' Fourteenth Affirmative Defense did not put the NYAG "on notice" of its preemption defense, that would not be fatal to the defense. As this Court has made clear, an affirmative defense "is not waived if it was raised at a pragmatically sufficient time, and the plaintiff was not prejudiced in its ability to respond." *Julio & Sons Co. v. Travelers Cas. and Sur. Co. of Am.*, 984 F. Supp. 2d 330, 339 (S.D.N.Y. 2010) (internal citations, quotation marks, and brackets omitted). The NYAG has not and cannot demonstrate that it was prejudiced in its ability to respond to Defendants' preemption defense.

The NYAG's substantive arguments in opposition to Defendants' preemption defense are similarly unavailing. Most glaringly, the NYAG attempts to argue that the FDCA, as amended by DSHEA, does not preempt state law claims for deceptive advertising because deceptive advertising is subject only to the FTC Act. (Opp. at 46—49.) But that argument entirely ignores that the FTC Guidance—which sets forth the standard for substantiating claims regarding dietary supplements—was issued *in response* to DSHEA. (Graham Decl. Ex. F, FTC Guidance at 1 (stating that the FTC Guidance was issued to answer the "many questions" DSHEA generated "about the FTC's approach to dietary supplement advertising").) Indeed, while Plaintiffs have attempted to distance themselves from the FDCA, DSHEA and FDA law more generally throughout this litigation, the NYAG now not only concedes its significance, but affirmatively (and repeatedly) relies on it in Response to Defendants' Rule 56.1 Statement. (CSOF ¶¶ 11, 56—59, 62, 109.) By the NYAG's own admission, then, the standards articulated in the FDCA and DSHEA are relevant to assessing the advertising claims brought by the NYAG, and the NYAG's attempt to argue that Quincy was required to conduct a specific drug-level type of RCT to substantiate its claims—a requirement that appears nowhere in the FTC Guidance, the FDCA, or the DSHEA (or the FTC Act)—is unquestionably preempted. (Mot. at 43—44, discussing *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 537 (S.D.N.Y. 2008) and *Bimont v. Unilever U.S., Inc.*, No. 14 Civ. 7749, 2015 WL 5259688, at *7-8 (S.D.N.Y. Sept. 9, 2015).[31]

The NYAG's remaining arguments do not move the needle. The NYAG argues that its claims for deceptive practices and false advertising fall within areas traditionally governed by the

[31] Plaintiffs' efforts to distinguish these cases are unpersuasive and should be ignored. Plaintiffs largely point to dicta where the reviewing courts posit instances where state law claims *may* not be preempted. But this is not the situation at bar. Here, like in these cases and the others cited in Defendants' opening brief, Plaintiffs are premising their state law claims on "requirements that are not parallel to those imposed by federal law" and such claims must be dismissed.

states' police powers and, accordingly, there is a presumption against preemption. (Opp. at 48.) But "the presumption generally does not apply to a sphere 'where there has been a history of significant federal presence.'" *Gayle v. Pfizer, Inc.*, 452 F. Supp. 3d 78, 87 (S.D.N.Y. 2020) (quoting *N.Y. SMSA Ltd. P'Ship v. Town of Clarkstown*, 612 F.3d 97, 104 (2d Cir. 2010)). It cannot be disputed that there has been—and continues to be—a significant federal presence in the area of regulating the advertisement and labeling of dietary supplements and, accordingly, any presumption against preemption does not apply here. *Id.* at 88 (finding that the FDCA and FDA regulations preempted state claims challenging the labeling of cholesterol management drug).

Similarly, the NYAG argues that this Court should not find preemption because the NYAG's claims "exist separate and apart from the FDCA and DSHEA." (Opp. at 49.) But the cases cited by the NYAG all involve scenarios where the FDCA had not addressed or issued any clear standards for the products challenged by state law claims. *See Lara v. Cool Clouds Distribution, Inc.*, No. 20-8030, 2021 WL 613842, at *9 (D.N.J. Feb. 16, 2021) (rejecting preemption argument over product liability case brought under state law where FDCA had not passed "design or product standards" for the products at issue); *Elkind v. Revlon Consumer Prods. Corp.*, No. 14 CV 2484, 2015 WL 2344134, at *7-8 (E.D.N.Y. May 14, 2015) (rejecting preemption argument over state claims brought challenging cosmetics labels where the FDCA and its regulations did not address that issue); *Morelli v. Weider Nutrition Grp.*, 275 A.D.2d 607, 607 (1st Dep't 2000) (rejecting preemption argument where, unlike here, no parallel claims brought under the applicable federal statute and state claims did not impose liability for conduct sanctioned by federal statute). Here, in contrast, the applicable federal law and regulations have specifically endeavored—through the "defined standards" outlined in the FTC Guidance—to regulate the product in question and, accordingly, the claims all overlap.

Plaintiffs' arguments that the "safe harbor" provisions in New York General Business Law §§ 349 and 350 somehow do not apply here fail for similar reasons. It is undisputed that these statutes provide for a "complete defense" against claims contending that certain practices violate New York law where those practices are permitted by federal law. (Opp. at 50.) It is also undisputed that New York law expressly incorporates the standards imposed by the FDCA, providing that conduct that complies with federal law and regulations necessarily complies with New York law. *See Izquierdo v. Mondelez-Int'l, Inc.*, No. 16 Civ. 04697, 2016 WL 6459832, at *3-4 (S.D.N.Y. Oct. 26, 2016). And it is undisputed that the NYAG is attempting to hold Quincy to a higher substantiation standard than called for by the FDCA and DSHEA (and even the FTC Act) by arguing that a drug-level RCT is required to substantiate its claims about Prevagen. There are no issues of fact that preclude summary judgment on this point; indeed, this is precisely the situation contemplated by the "safe harbor."

VI. THE NYAG CONCEDED ITS INABILITY TO RECOVER RESTITUTION ON BEHALF OF CONSUMERS WHOSE CLAIMS WERE RELEASED AS PART OF THE *COLLINS* SETTLEMENT

In their moving brief, Defendants argued that "the NYAG is not entitled to recover restitution on behalf of New York residents who purchased Prevagen prior to the *Collins* Settlement" because those consumers' claims were released as part of the *Collins* Settlement. (Mot. at 45; Graham Decl. Exs. HH, JJ.) Despite purporting to oppose this argument (Opp. at 51—52), the NYAG expressly concedes this exact point in its Response to Defendants' Rule 56.1 Statement, when it repeatedly asserts that "neither Plaintiff is seeking restitution on behalf of consumers covered by the class action settlement." (Pl. Add'l Facts ¶¶ 39—44, 51.) Thus, the Parties are in agreement that Defendants are entitled to summary judgment dismissing the NYAG's claim for restitution to the extent such a claim applies to New York residents who purchased Prevagen prior to, and therefore are bound by, the *Collins* Settlement. Plaintiffs' additional claim

for restitution on behalf of New York consumers who purchased Prevagen *after* the *Collins* Settlement is barred for the same reasons discussed above, namely that Plaintiffs have to offer any evidence that the Qualifier failed to cure the allegedly deceptive "net impression" of Defendants' advertising. (*See* Section. II.D, *supra.*)

CONCLUSION

For the foregoing reasons, and for the reasons set forth in their moving papers, Defendants respectfully request that the Court grant their motion and enter summary judgment in Defendants' favor with respect to each of Plaintiffs' claims with prejudice.

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